United States Animal Health Association
Biologics & Biotechnology Committee

Steven A. Karli
Director
USDA, APHIS
Veterinary Services
Center for Veterinary Biologics
Inspection and Compliance

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Updates

- **Program Information Management and Security**
  - Automated Information Management System
  - eAuthentication
  - Continuity of Operations Planning

- **Quality Management**
  - Activities
  - Vision Statement

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Updates

- **Inspection**
  - Administrative Inspection Review
  - Export Activities
  - FY Numbers
    - Inspections
    - Serial Release
- **Compliance**
  - Current Issues
  - Pharmacovigilance

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Program Information Management and Security

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Automated Information Management System (AIMS)

- Phase 2 : Licensing, Serial Release, and Testing (LSRTIS) Project Mission
  - Replace our current information systems with an integrated system that is flexible, reliable, supportable, efficient, adaptable, accessible, secure, cost effective, and tailored to the current and future needs of CVB and their customers/stakeholders.

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Automated Information Management System (AIMS)

- Phase II of LSRTIS
  - Replace legacy system and core functions
    - Release 1
      - IC serial Release functions
      - PEL testing & scheduling functions
      - Biological Materials Processing Section (BMPS) CVB functions
    - Release 2
      - Facilities
      - Compliance
      - Export

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Automated Information Management System (AIMS)

- Timeline Release 1
  - Phase II project initiated October 2004
  - Implementation expected April 07
- Enhancements
  - Increased tracking capability
  - Firm services
  - Technological advancements

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Automated Information Management System (AIMS)

Portal Entry for Firm Services

- e Authentication Account
  - Allows access to applications
- Level 2 Access
  - provides the ability to conduct official electronic business transactions with the USDA via the Internet
  - Biologics Specialists to be used as LRA

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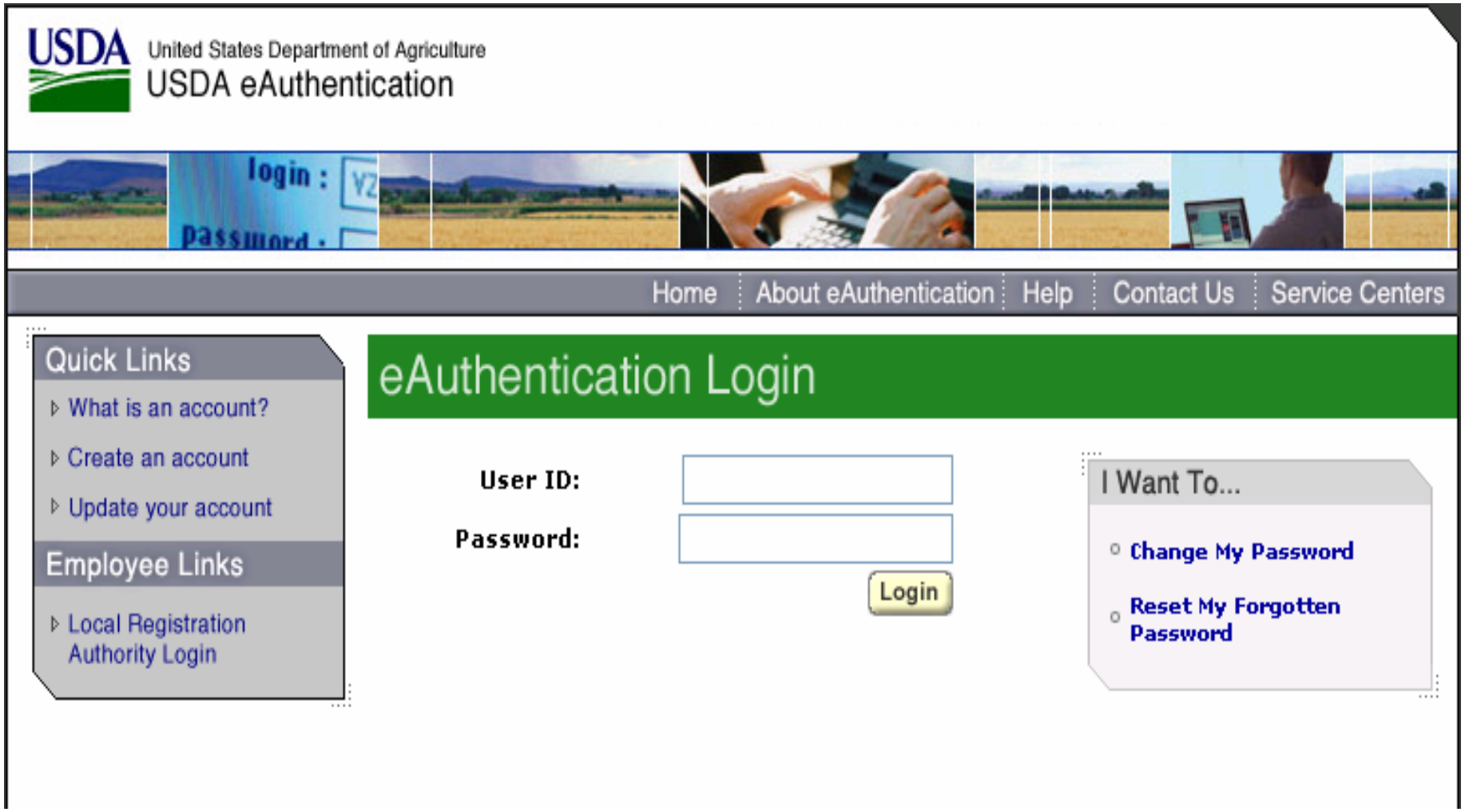

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Automated Information Management System (AIMS)

- Future Challenges
  - APHIS Form 2008 currently a Level 3 application
    - No solution from USDA/APHIS for Level 3 applications
  - Signatures/Authentication
    - No solution from USDA/APHIS for electronic signatures
  - Budget vs end product
    - May have to phase projects

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Continuity of Operations Plan (COOP)

- Mission Critical Business Processes
  - Essential Functions
  - Business Recovery Plan
  - Living Disaster Recovery Planning System (LDRPS)
    - Scanning of Outlines of Production
      - Special Outlines
      - Outlines of Production

Quality Management

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CVB QUALITY VISION STATEMENT

January 1, 2005

The Center for Veterinary Biologics (CVB) reaffirms its commitment to a quality-based program as an integral component of the CVB Mission and Vision. Quality management is the responsibility and fundamental duty of every employee at the CVB. The CVB Quality goal is to embrace and sustain a documented program of procedures and process improvement which results in services and products that consistently meet or exceed the needs and expectations of its customers and stakeholders.

- The Quality Objective of the Policy, Evaluation, and Licensing (PEL) laboratory staff is to ensure that the testing services and reagents provided are of the highest quality and are well supported by documentation. This will be accomplished by systematically developing a quality structure that ensures and promotes scientific excellence in an environment of well-defined processes.
- The Quality Objective of the PEL review staff is to ensure fair, consistent, and comprehensive review and evaluation of product development and production data submitted by veterinary biologics manufacturers in support of product licensure for compliance with the Virus-Serum-Toxin Act and associated Federal regulations. Policy will be consistent, well documented, and based on sound science.
- The Quality Objective of the Inspection and Compliance staff is to ensure that veterinary biological products are prepared, maintained, and distributed in compliance with the Virus-Serum-Toxin Act and associated Federal regulations. The documentation and processes for the assessment of establishment procedures, facilities, and product distribution will fulfill evolving Federal requirements for biosafety, biosecurity, agent accountability, and environmental protection.

VS

Richard E. Hill, Jr., Director
Policy, Evaluation, and Licensing
Center for Veterinary Biologics

Steven A. Karli, Director
Inspection and Compliance
Center for Veterinary Biologics

APHIS

Quality Management

- Personnel
  - Section Leader
  - 3 Biologics Specialists
  - Quality Management Assistant
- Quality Manual
- Reference and Reagent production, review, and release process expanded
- Development of Process Audits at the Center
- Training in ISO 9001:2000 and 17025:2005 standards for all CVB personnel has been scheduled

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Inspection

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Administrative Inspection Review (AIR)

- Administrative Reviews – CY2005
  - 61 reviews have been sent to the firms
  - Has helped CVB maintain current updated information in our information systems
  - Firms keep current in their own review
  - Firms able to schedule resources on their own time table vs. an On-Site Inspection

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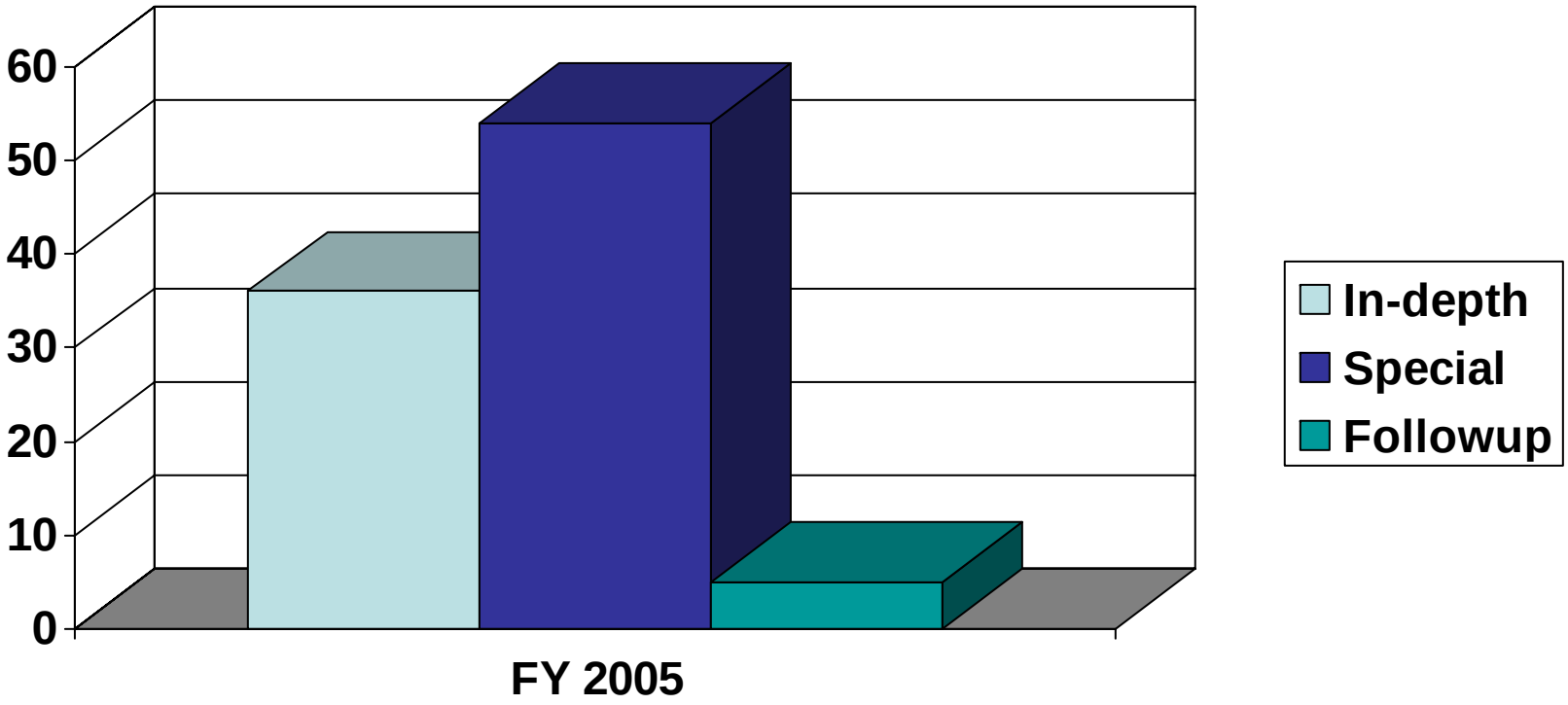
Administrative Inspection Review

- Outcomes of the Administrative Reviews:
  - Longer time frame for review and action by the firms
    - From 30 to 45 days
  - Inspections can now focus on product preparation, testing and initial distribution
  - Inspectors are potentially on site for a shorter period of time
- What's Next?
  - Yearly review for all licensed and permitted firms

Inspections



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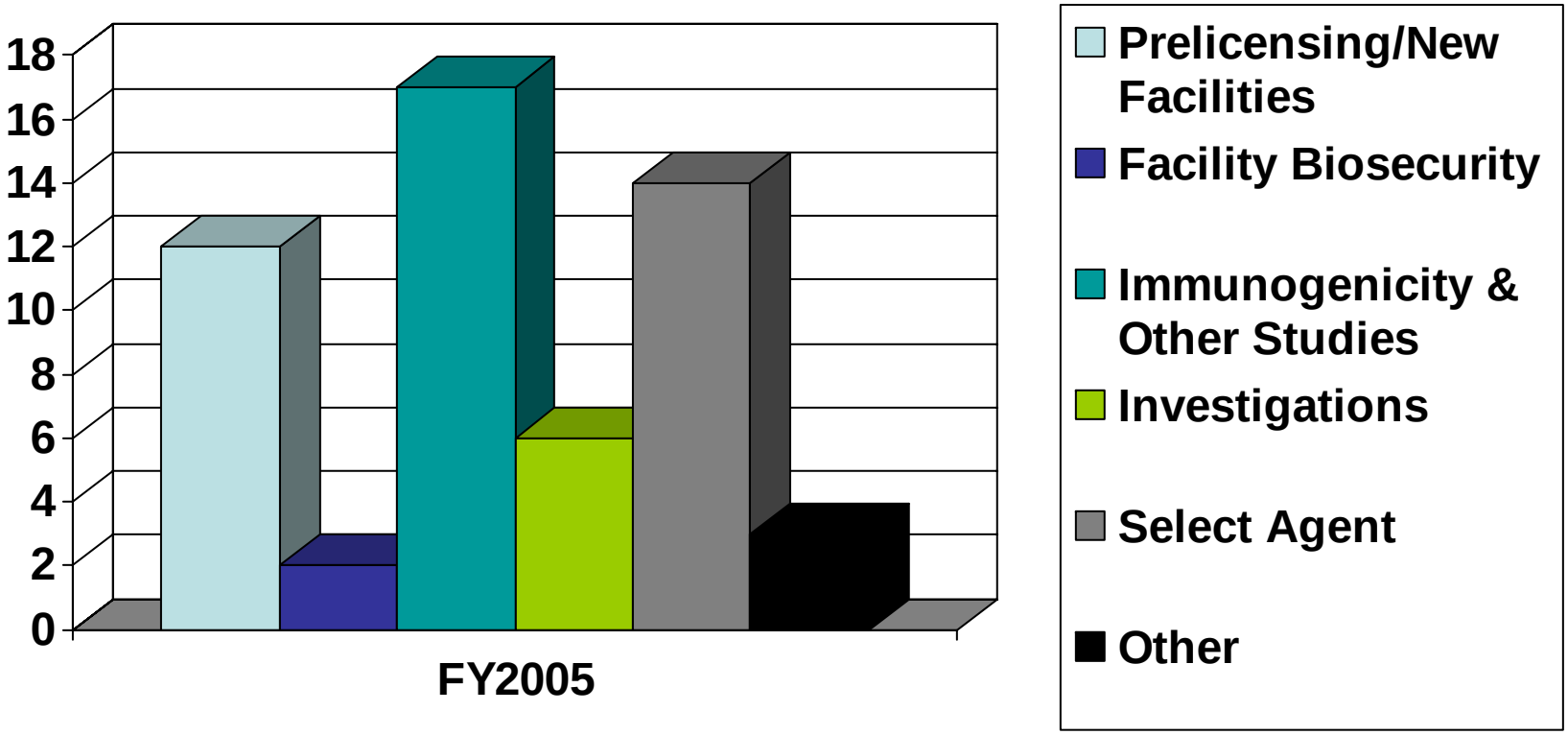
Special Inspections



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Exporting Veterinary Biologicals

- CVB certifies VS Forms 2017, 2046, 2046S, 2047 and 2047S to assist manufacturers of veterinary biologicals in exporting licensed products to other countries
  - **2017**; Export Certificate
  - **2046 and 2047**; Certificate of Licensing and Inspection
  - **2046S and 2047S**; Spanish versions of the Certificate of Licensing and Inspection

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Export Certificates

- These forms certify
  - That the veterinary biological listed is intended for use in the treatment of animals
  - That the product is licensed by CVB
  - That the product has been produced in a CVB licensed establishment
  - That the product suitable for use in the U.S.

Export Activities

- Following the positive BSE in the US
  - CVB worked with International Services and the National Center for Import and Export to resume the exportation of veterinary biologicals to other countries
  - Current and Resolved Issues
    - Chile, Mexico, Brazil
  - Joint inspection of US Biologics Manufacturers
    - CVB and Brazilian Regulatory Officials

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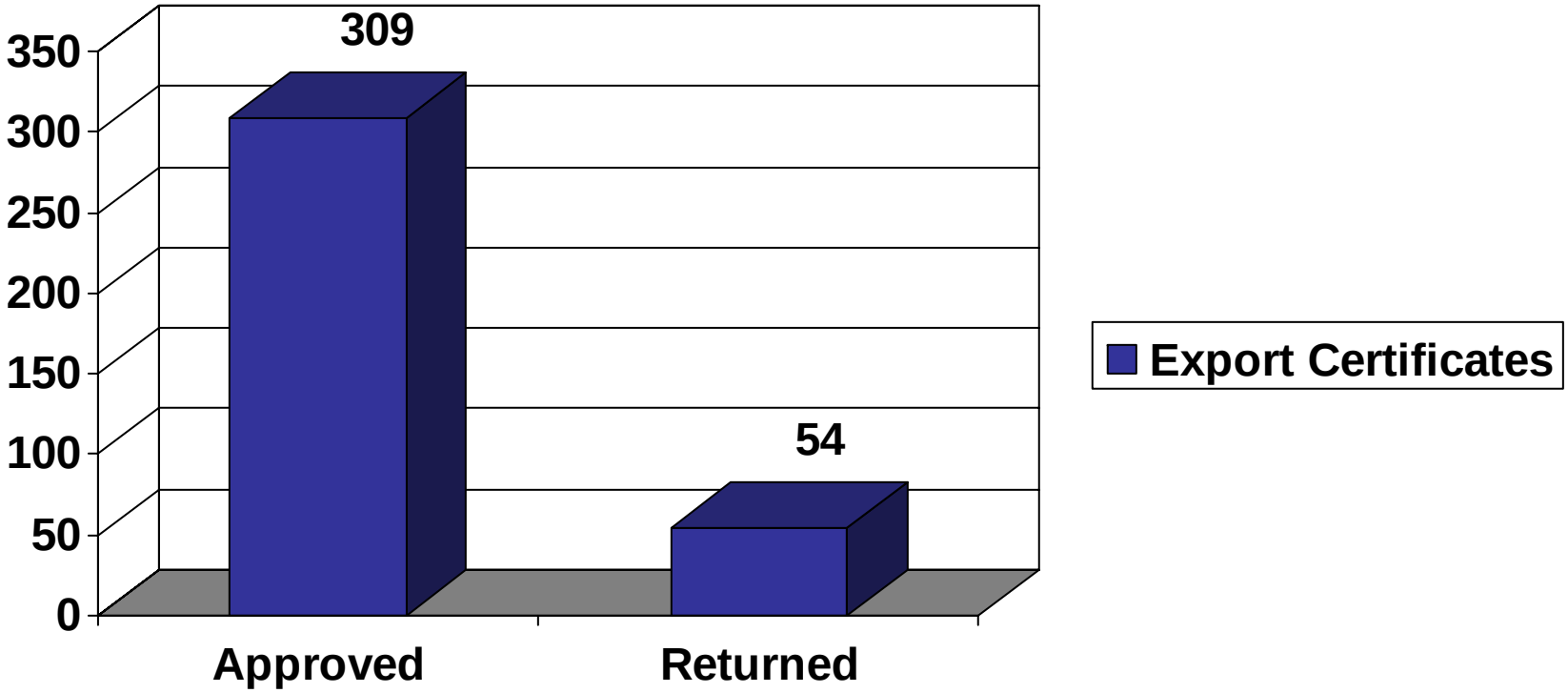
Export Activities by Serial – FY 05



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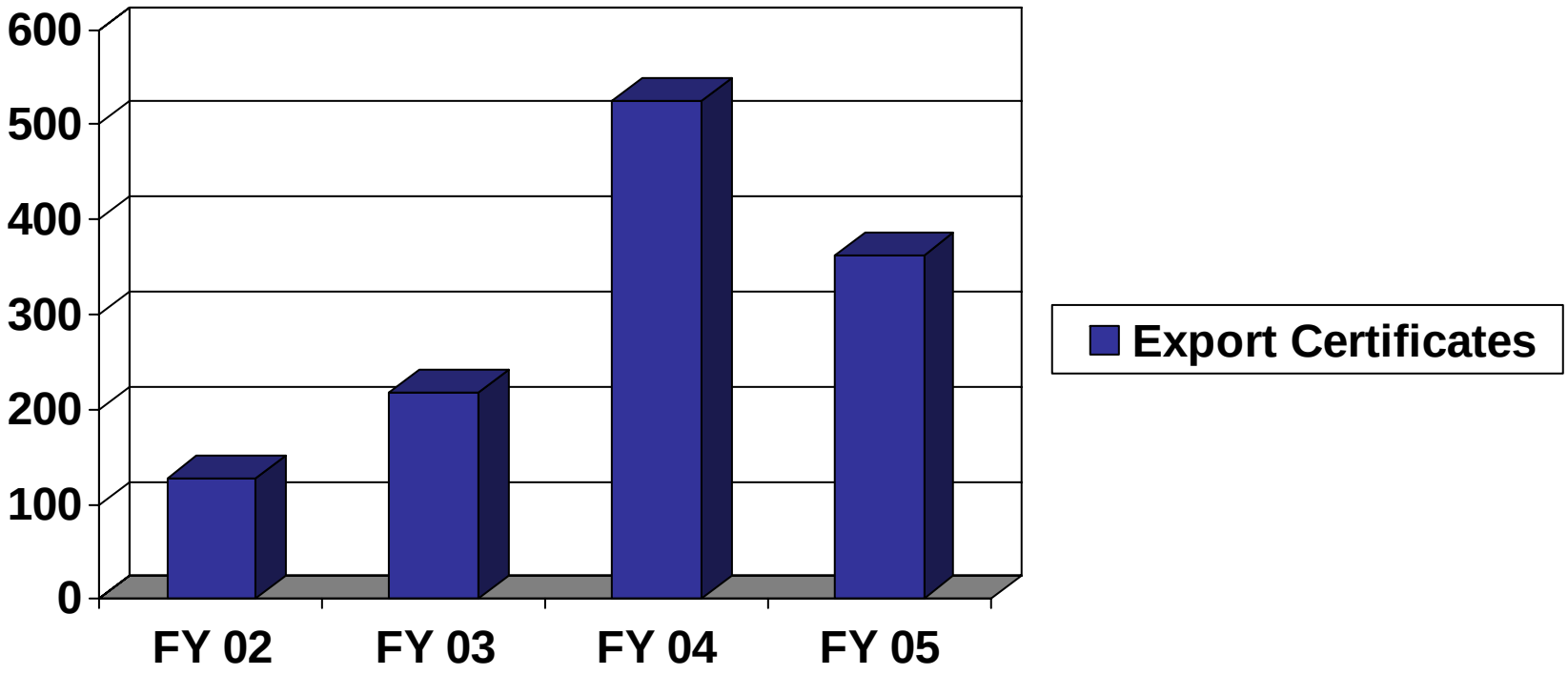
Export Activities by Serial



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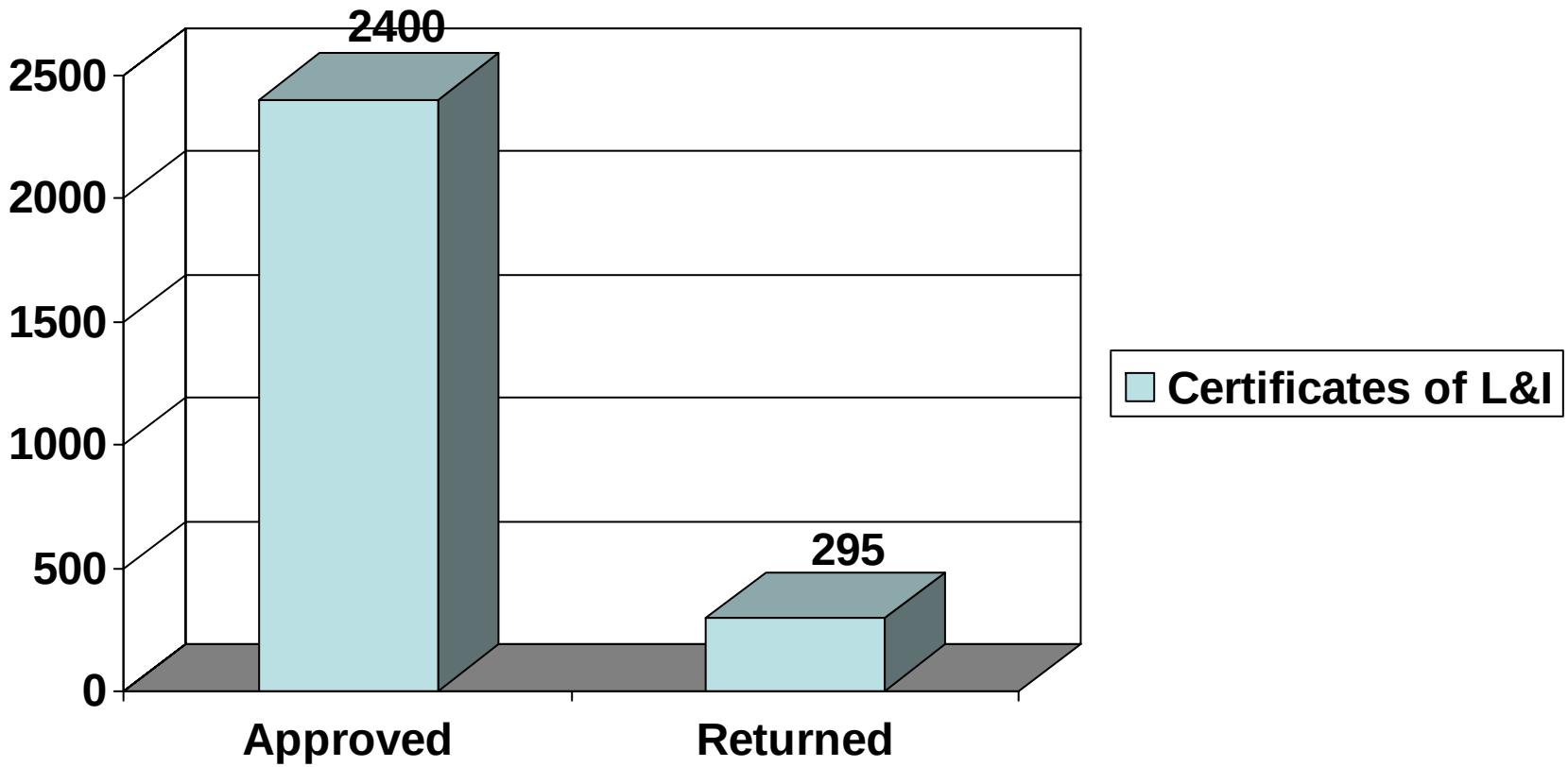
Export Activities by Product – FY 05



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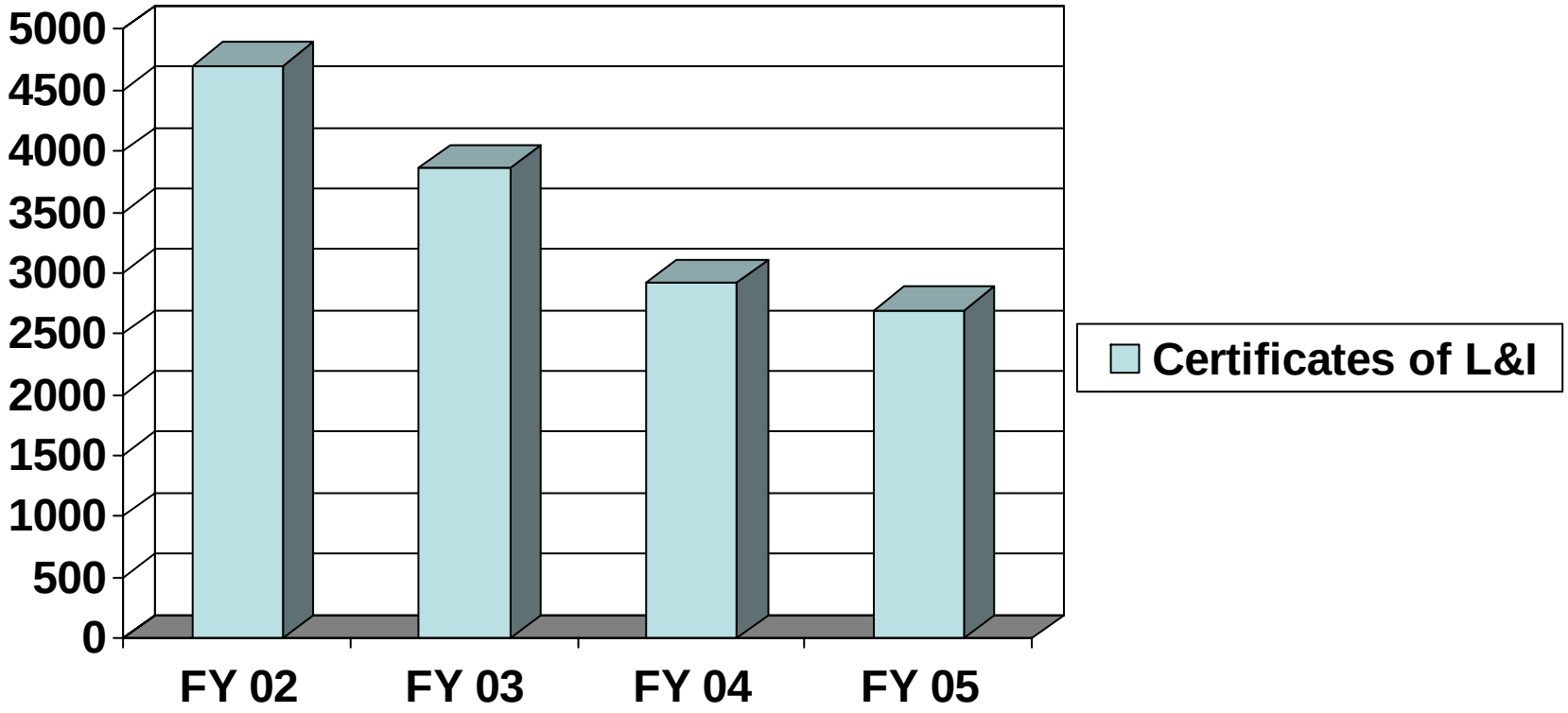
Export Activities by Product



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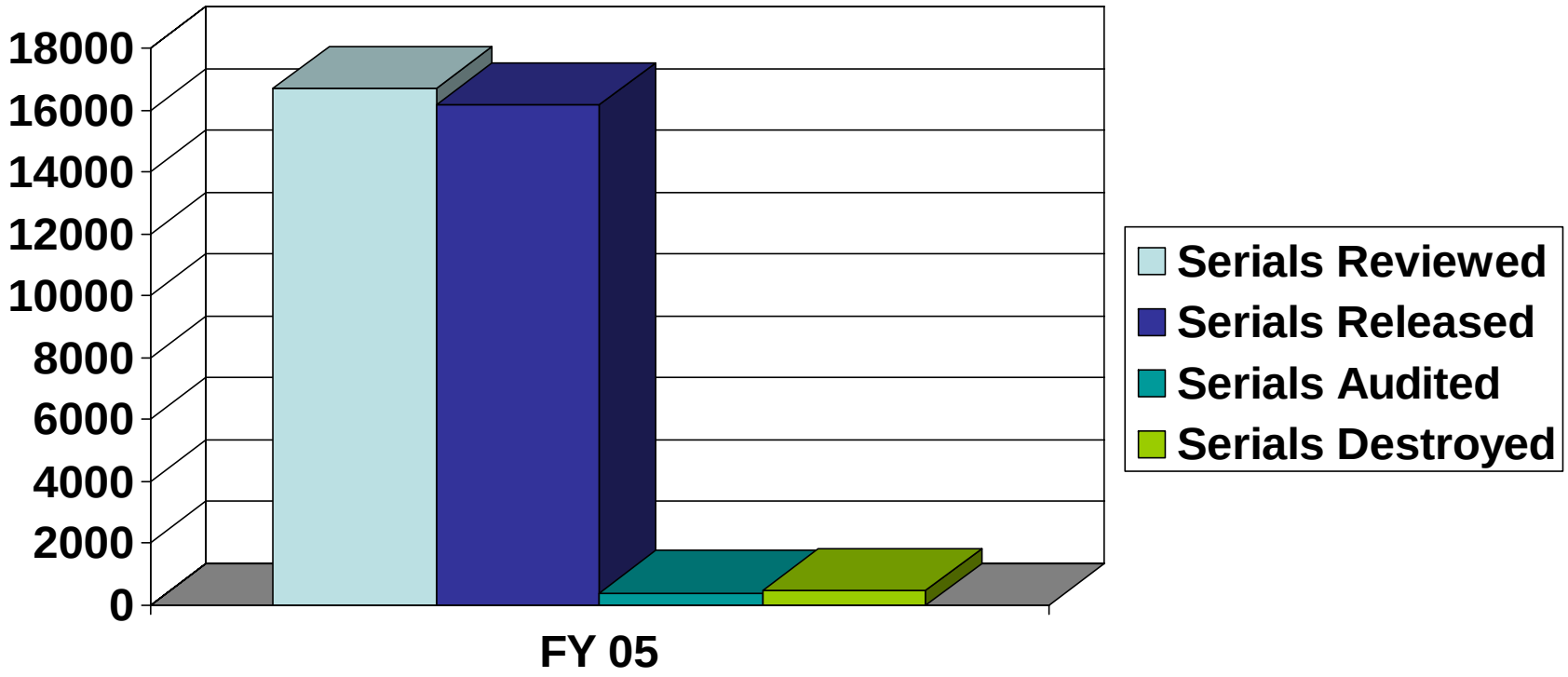
Serial Release Activities – FY 05



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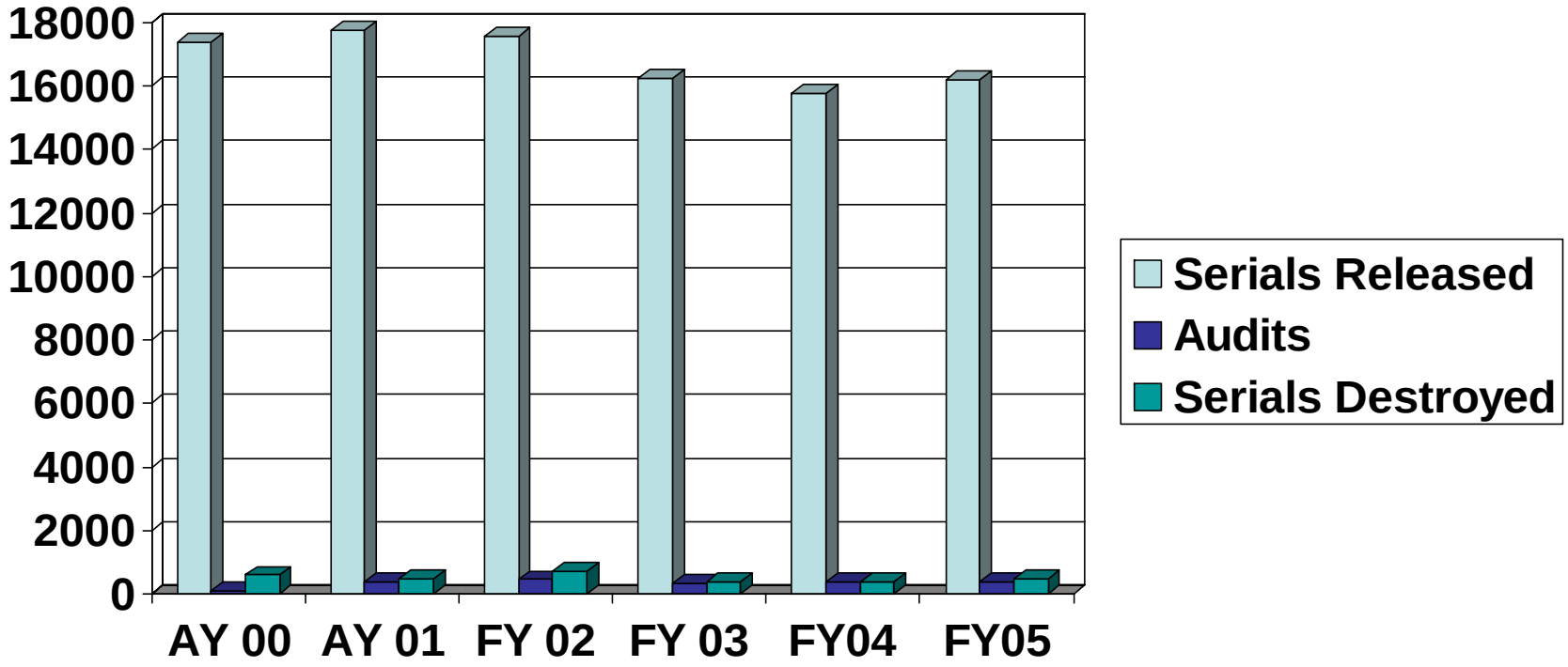
Serial Release Activities



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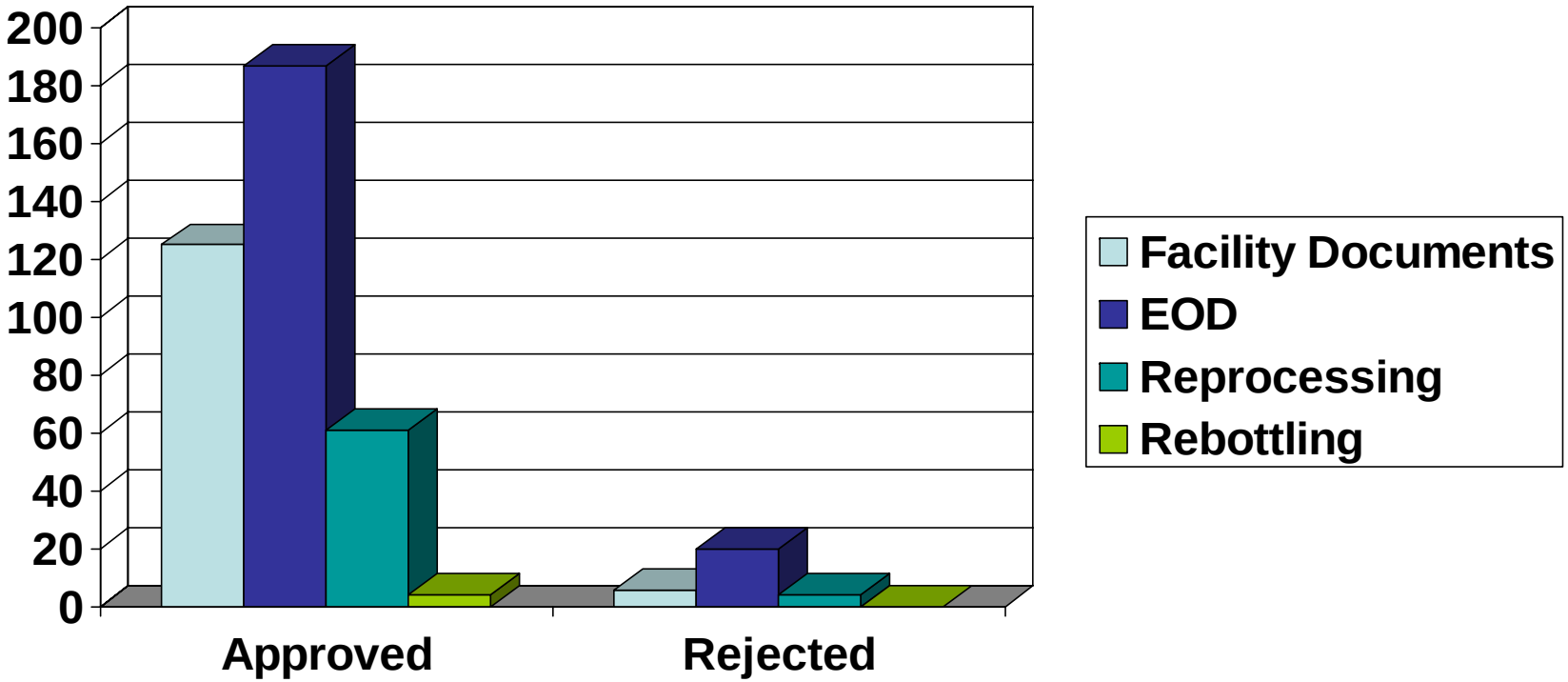
Product Inspection Activities – FY 05



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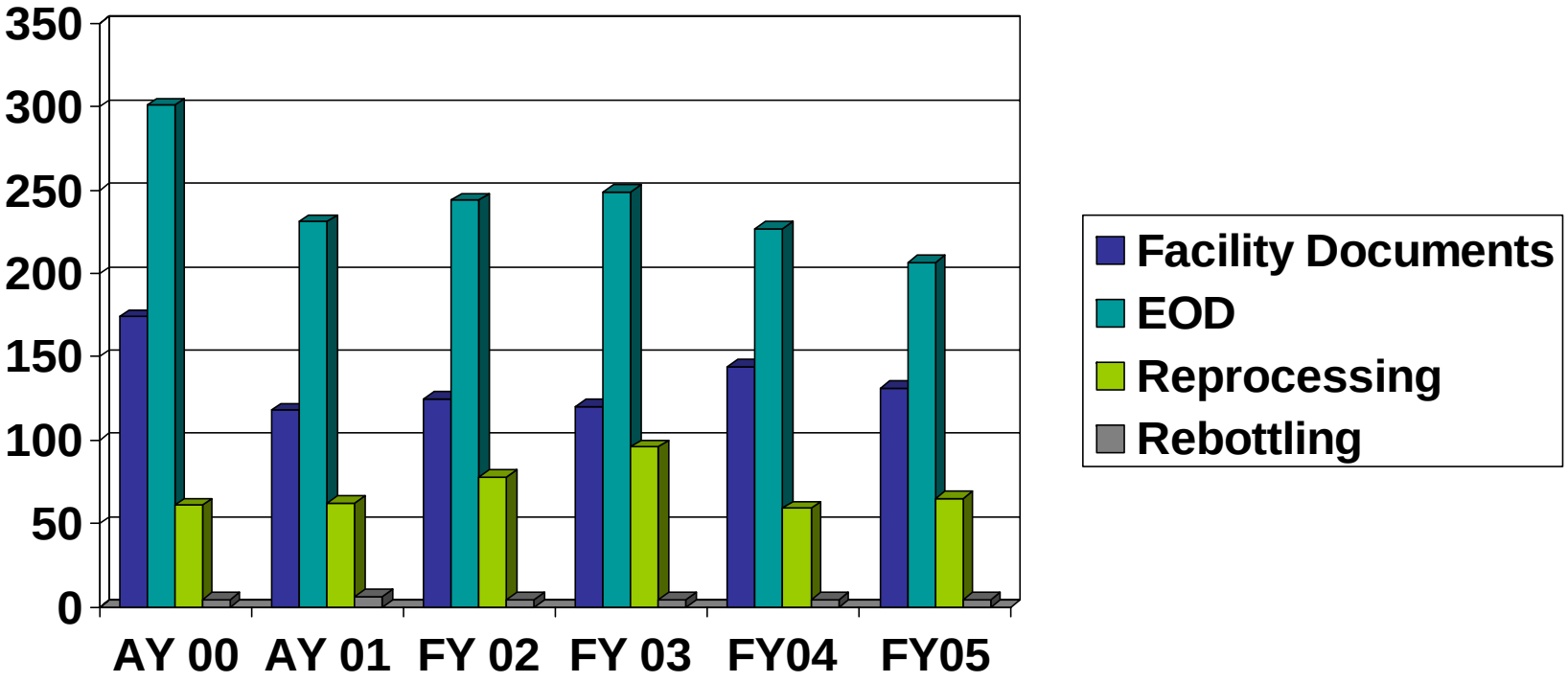
Product Inspection Activities



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Compliance

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Primary Sources of Compliance Issues- Investigations

- Advertising
- Inaccurate/incomplete/false reports
- Potency/Stability problems
- Egg outbreaks
- Unlicensed manufacture

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Primary Sources of Compliance Issues- Regulatory Actions

- Hold Release letters (42 vs. 6)
- Voluntary Stop Sales (40 - 26)
- APHIS-Mandated Stop Sales (21 – 2)
- Letters of Advice (11-7)

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Primary Sources of Compliance Issues- Informal Actions

- Infraction Notices (26 vs 11)
- Letters of Warning (5 vs. 4)

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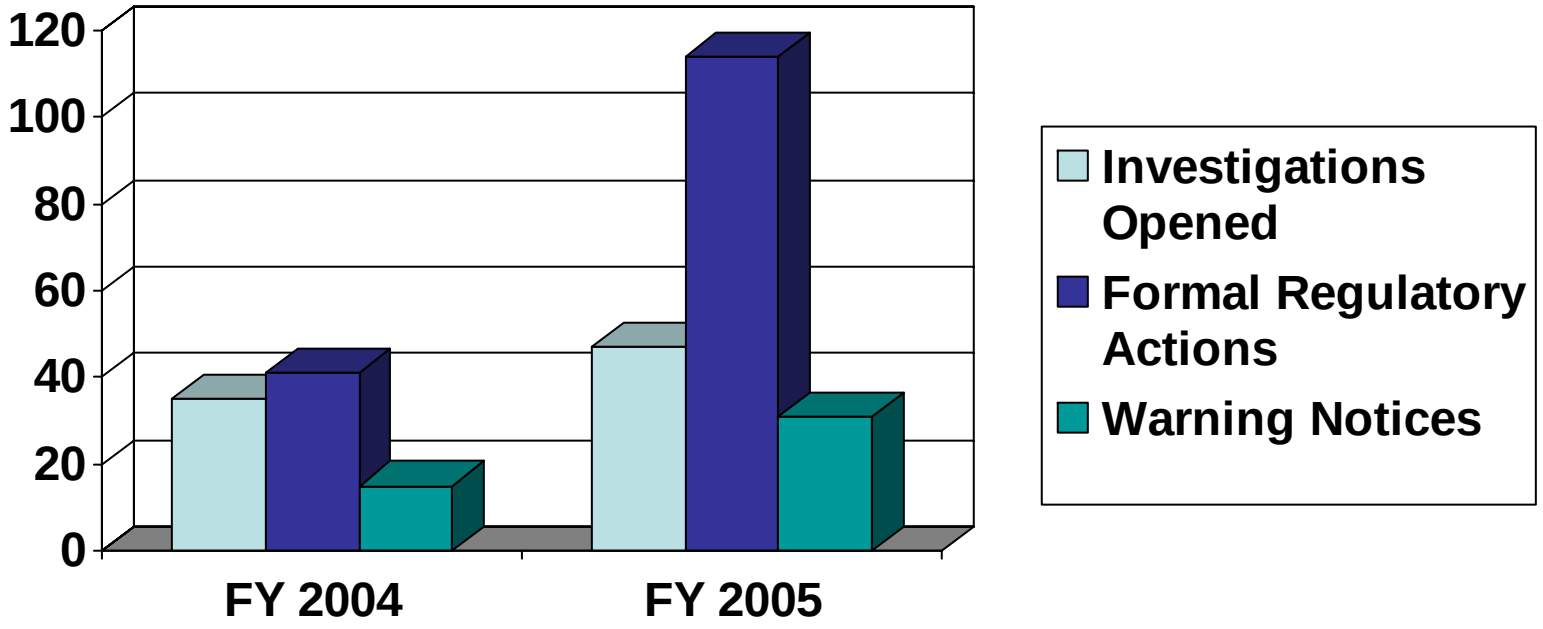
Regulatory Actions



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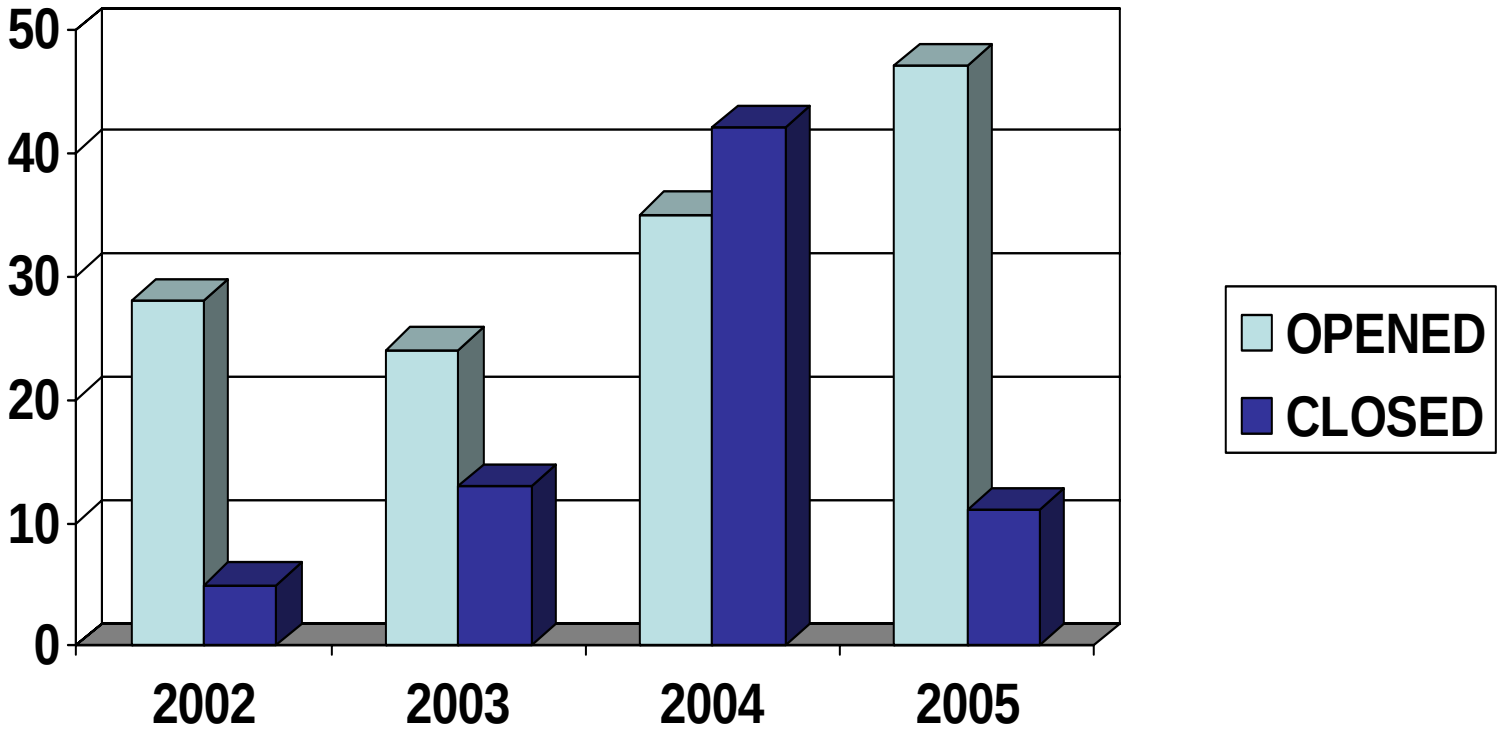
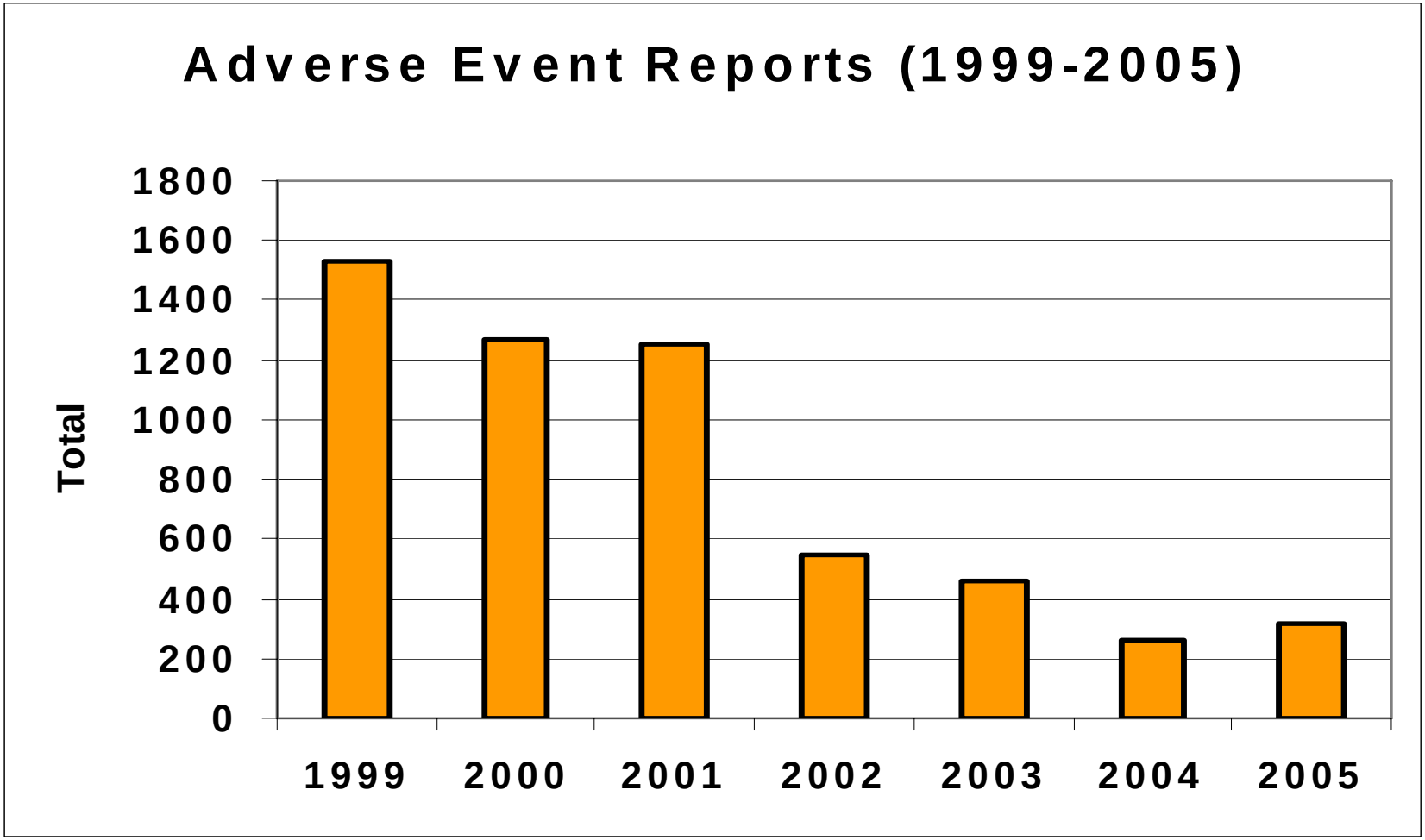
Investigations, FY 2005





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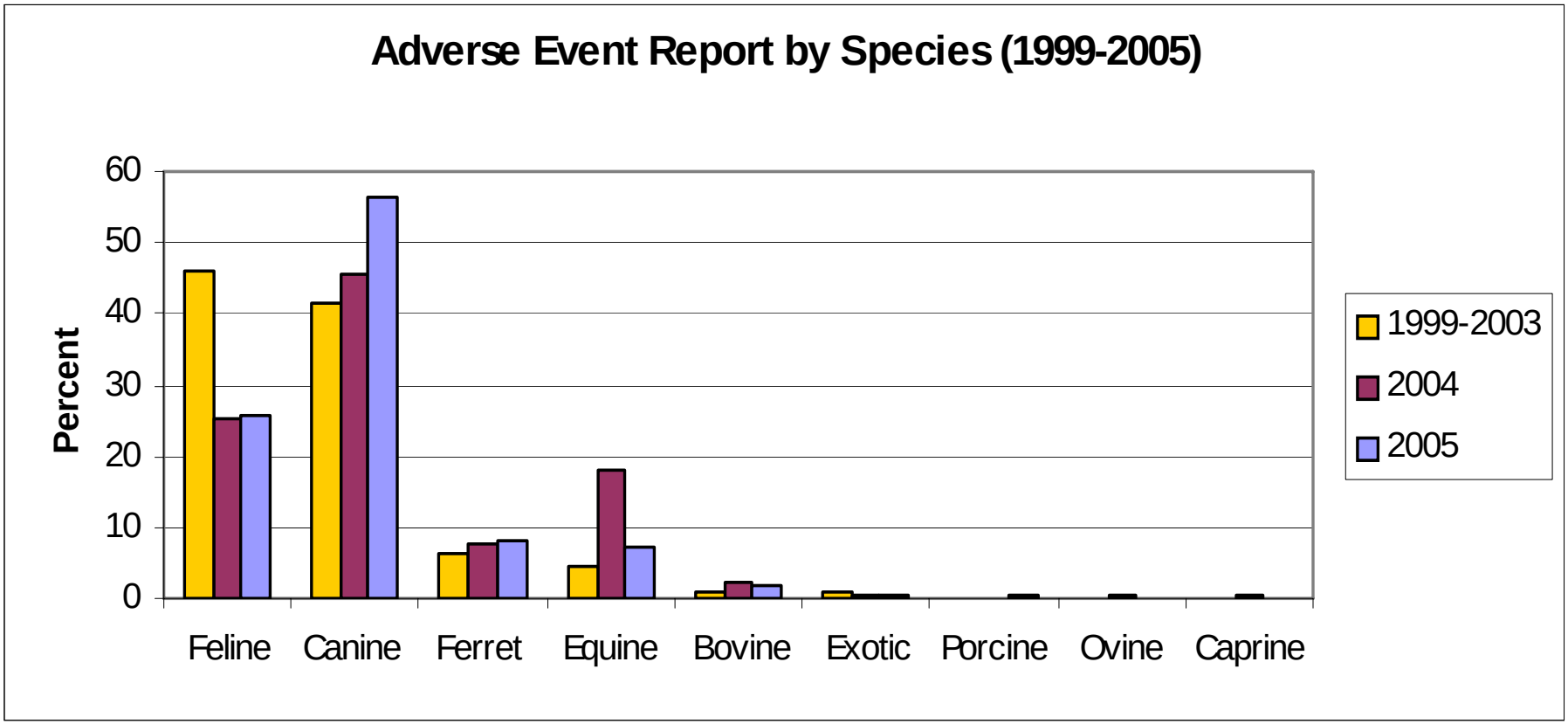

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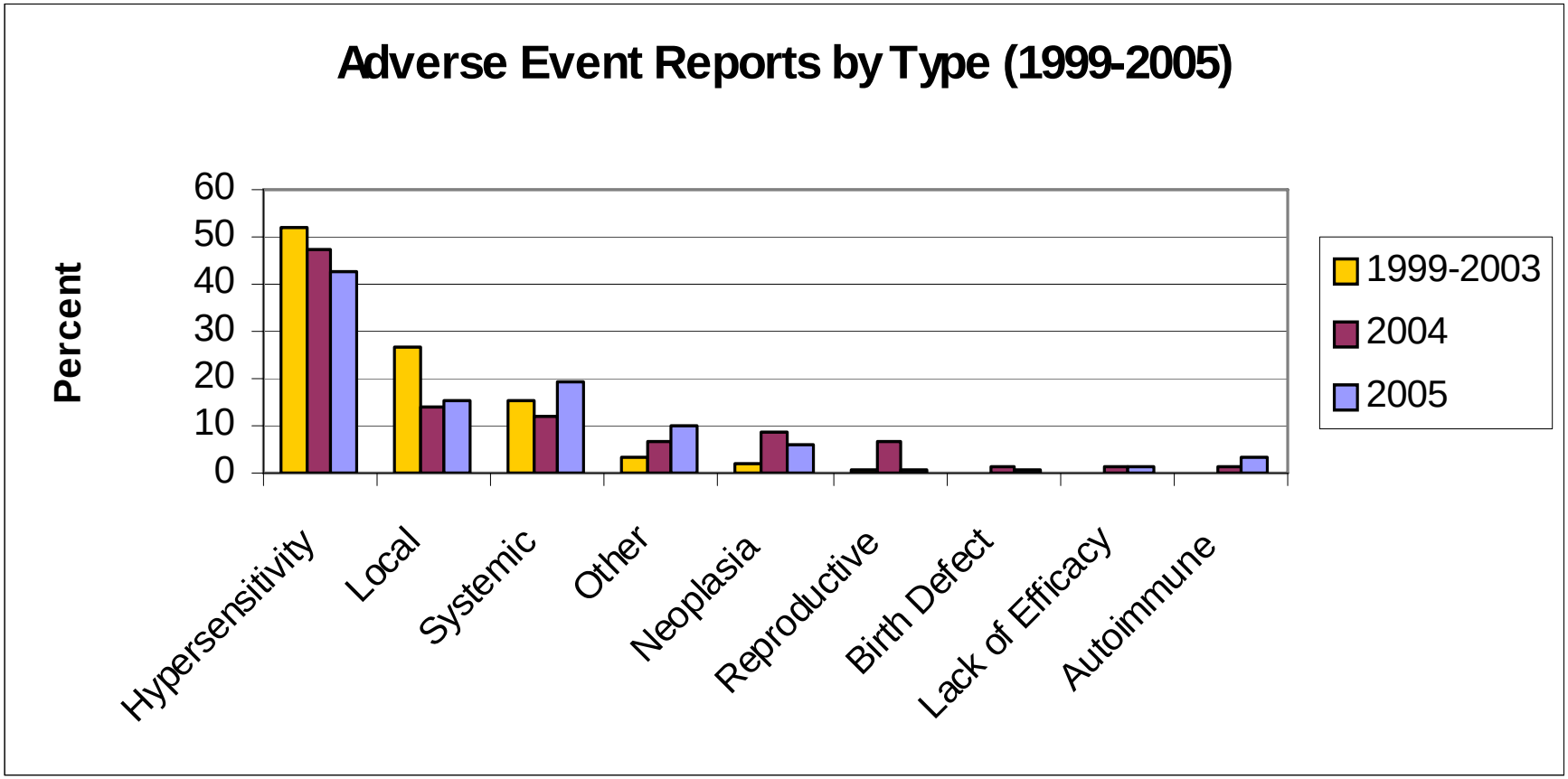

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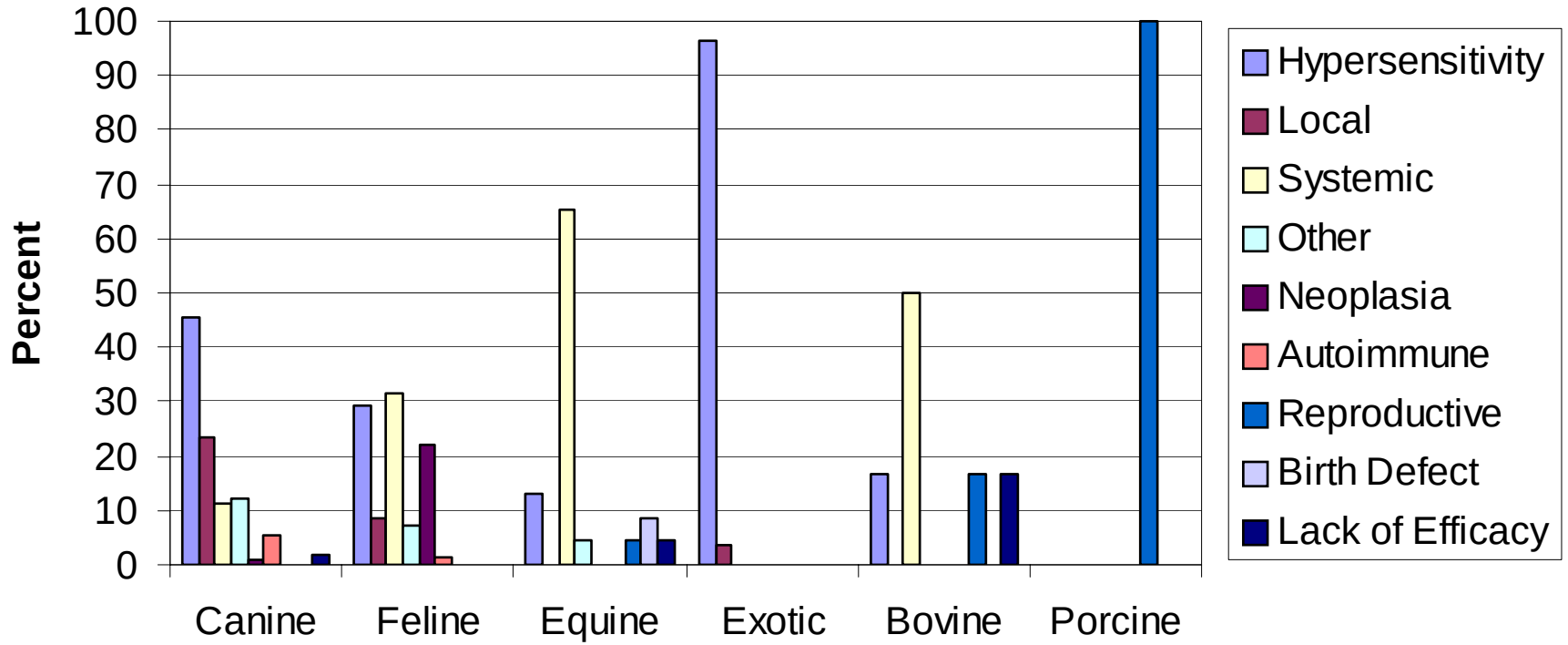
Adverse Event Reports: Type by Species (2005)



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Additional Compliance Issues

- Owner-Exempted “Planned Exposure”
  - 9 CFR 107.1
  - PRRS
  - Coccidiosis, poultry
- Autogenous Vaccines
  - Extensions; adjacent and non-adjacent use
- Notice on Immediate Notification

Pharmacovigilance

- Federal Register – Proposed Rule published
  - Comment period closed
  - Evaluating comments for next steps
- VICH Harmonization activities –
  - Progress made at recent Expert Working Group meeting in London, October 2005

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CVB Website

- www.aphis.usda.gov/vs/cvb
- To file an Adverse Event Report
  - Click on “Vaccine Adverse Events” button
- CVB guidance documents
- Links to current BSE Surveillance System information

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